

James H. Neale (JN6972)  
FULBRIGHT & JAWORSKI L.L.P.  
666 Fifth Avenue  
New York, New York 10103  
(212) 318-3000  
*Attorneys for Defendants*

- and -

Terry O. Tottenham  
Lana K. Varney  
FULBRIGHT & JAWORSKI L.L.P.  
600 Congress Avenue, Suite 2400  
Austin, Texas 78701  
(512) 536-5201  
*Of Counsel*

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY  
LITIGATION – MDL NO. 1789

SALLY M. GROVOM, X

Plaintiff,

v.

MERCK & CO., INC., PROCTER &  
GAMBLE PHARMACEUTICALS, INC.  
AND AVENTIS PHARMACEUTICALS,  
INC.,

Defendants.

MASTER FILE:  
1:06-MD-01789-JFK-JCF

CIVIL ACTION NO. 1:07-CV-8151

**ANSWER**

Procter & Gamble Pharmaceuticals, Inc. (“P&G”) and sanofi-aventis U.S. L.L.C. (“sanofi-aventis”), successor in interest to Aventis Pharmaceuticals, Inc., answer Plaintiff Sally M. Grovom’s (“Plaintiff”) Original Complaint (“Complaint”) as follows:

1. In answer to paragraph 1 of the Complaint, P&G and sanofi-aventis admit that this is a civil action for alleged damages suffered by Plaintiff Sally M. Grovom. However, P&G

and sanofi-aventis deny that Plaintiff has suffered any damages as a result of her allegedly being prescribed and her alleged ingestion of the medication Actonel.

**PARTIES**

2. In answer to paragraph 2 of the Complaint, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

3. The allegations in paragraph 3 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

4. In answer to paragraph 4 of the Complaint, Defendant P&G admits that it is an Ohio corporation with its principal place of business in Cincinnati, Ohio. Defendant P&G denies any remaining allegations.

5. In answer to paragraph 5 of the Complaint, Defendant sanofi-aventis admits that it is a Delaware corporation with its principal place of business in New Jersey. Defendant sanofi-aventis denies any remaining allegations.

6. In answer to paragraph 6 of the Complaint, P&G and sanofi-aventis admit that they conduct business in the States of New York and Washington. P&G and sanofi-aventis deny any remaining allegations.

**JURISDICTION**

7. In answer to paragraph 7 of the Complaint, P&G and sanofi-aventis admit that jurisdiction is proper in federal court. P&G and sanofi-aventis further admit that Plaintiff, upon information and belief, and P&G and sanofi-aventis are citizens of different states. Although

they deny Plaintiff is entitled to any damages whatsoever, P&G and sanofi-aventis admit that, upon information and belief, the amount in controversy appears to be greater than \$75,000.

### **FACTUAL BACKGROUND**

#### **FOSAMAX**

8. The allegations in paragraph 8 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

9. The allegations in paragraph 9 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

10. The allegations in paragraph 10 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

11. The allegations in paragraph 11 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

12. The allegations in paragraph 12 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required,

P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

13. The allegations in paragraph 13 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

14. The allegations in paragraph 14 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

15. The allegations in paragraph 15 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

16. The allegations in paragraph 16 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

17. The allegations in paragraph 17 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

18. The allegations in paragraph 18 of the Complaint, including all sub-parts, are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

**ACTONEL**

19. In answer to paragraph 19 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis denies the remaining allegations contained in paragraph 19.

20. In answer to paragraph 20 of the Complaint, P&G and sanofi-aventis admit that Actonel is a brand name of risedronate sodium and that it is a prescription bisphosphonate that is taken orally. P&G and sanofi-aventis deny any remaining allegations.

21. In answer to paragraph 21 of the Complaint, P&G and sanofi-aventis admit that Actonel was approved by the United States Food and Drug Administration (“FDA”) for prevention and treatment of osteoporosis.

22. In answer to paragraph 22 of the Complaint, P&G and sanofi-aventis deny the allegations. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

23. P&G and sanofi-aventis deny the allegations contained in paragraph 23.

24. The allegations in paragraph 24 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis deny the allegations contained in paragraph 24 except to respectfully refer the Court to the referenced report for its true and complete contents.

25. The allegations in paragraph 25 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis deny the allegations contained in paragraph 25 except to respectfully refer the Court to the referenced documents for their true and complete contents.

26. In answer to paragraph 26 of the Complaint, P&G and sanofi-aventis deny the allegations. By way of further answer, P&G and sanofi-aventis state that the Actonel labeling and package inserts were approved by FDA and contained appropriate and adequate warnings in accordance with federal statutes and regulations and with the existing state of medical and scientific knowledge.

27. In answer to paragraph 27 of the Complaint, P&G and sanofi-aventis state that they lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations, and therefore deny the allegations contained therein.

28. P&G and sanofi-aventis deny the allegations contained in paragraph 28, including all separate subparts.

29. P&G and sanofi-aventis note that there is no paragraph number 29 in the Complaint.

**FIRST CLAIM FOR RELIEF**

**[Strict Product Liability – Design Defect]**

30. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 29 above.

31. The allegations in paragraph 31 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

32. The allegations in paragraph 32 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

33. The allegations in paragraph 33 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

34. The allegations in paragraph 34 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

35. The allegations in paragraph 35 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

36. The allegations in paragraph 36 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

37. In answer to paragraph 37 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis denies the remaining allegations contained in paragraph 37.

38. P&G and sanofi-aventis deny the allegations contained in paragraph 38.

39. P&G and sanofi-aventis deny the allegations contained in paragraph 39.

40. P&G and sanofi-aventis deny the allegations contained in paragraph 40.

41. P&G and sanofi-aventis deny the allegations contained in paragraph 41.

42. P&G and sanofi-aventis deny the allegations contained in paragraph 42.

#### **SECOND CLAIM FOR RELIEF**

##### **[Strict Product Liability – Failure to Warn]**

43. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 29 above.

44. The allegations in paragraph 44 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

45. The allegations in paragraph 45 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

46. The allegations in paragraph 46 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

47. The allegations in paragraph 47 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

48. In answer to paragraph 48 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis denies the remaining allegations contained in paragraph 48.

49. P&G and sanofi-aventis deny the allegations contained in paragraph 49.

50. P&G and sanofi-aventis deny the allegations contained in paragraph 50.

51. P&G and sanofi-aventis deny the allegations contained in paragraph 51.

**THIRD CLAIM FOR RELIEF**

[Negligence]

52. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 29 above.

53. The allegations in paragraph 53 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

54. The allegations in paragraph 54 of the Complaint are not directed to P&G and sanofi-aventis therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

55. The allegations in paragraph 55 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

56. The allegations in paragraph 56 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

57. The allegations in paragraph 57 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

58. In answer to paragraph 58 of the Complaint, Defendant P&G admits that it designed, tested, developed, manufactured, labeled, marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis admits that it marketed, distributed and sold Actonel in the United States. Defendant sanofi-aventis denies the remaining allegations contained in paragraph 58.

59. In answer to paragraph 59 of the Complaint, P&G and sanofi-aventis admit that they had a duty to comply with all applicable law, which they did. P&G and sanofi-aventis deny the remaining allegations contained in paragraph 59.

60. P&G and sanofi-aventis deny the allegations contained in paragraph 60.

61. P&G and sanofi-aventis deny the allegations contained in paragraph 61.

62. P&G and sanofi-aventis deny the allegations contained in paragraph 62.

#### **FOURTH CLAIM FOR RELIEF**

##### **[Breach of Express Warranty]**

63. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 29 above.

64. The allegations in paragraph 64 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

65. The allegations in paragraph 65 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

66. The allegations in paragraph 66 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

67. The allegations in paragraph 67 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

68. P&G and sanofi-aventis deny the allegations contained in paragraph 68.

69. In answer to paragraph 69 of the Complaint, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.

70. P&G and sanofi-aventis deny the allegations contained in paragraph 70.

71. P&G and sanofi-aventis deny the allegations contained in paragraph 71.

**FIFTH CLAIM FOR RELIEF**

**[Breach of Implied Warranty]**

72. P&G and sanofi-aventis incorporate by reference, as if fully set forth herein, the responses and defenses set forth in paragraphs 1 through 29 above.

73. The allegations in paragraph 73 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

74. The allegations in paragraph 74 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

75. The allegations in paragraph 75 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

76. The allegations in paragraph 76 of the Complaint are not directed to P&G and sanofi-aventis and therefore require no response from them. To the extent a response is required, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief as to the truth or falsity of the information asserted, and therefore, deny the allegations contained therein.

77. P&G and sanofi-aventis deny the allegations contained in paragraph 77.

78. In answer to paragraph 78 of the Complaint, P&G and sanofi-aventis lack knowledge and information sufficient to form a belief regarding the truth or falsity of the allegations asserted, and therefore deny the allegations contained therein.

79. P&G and sanofi-aventis deny the allegations contained in paragraph 79.

80. P&G and sanofi-aventis deny the allegations contained in paragraph 80.

**PRAYER FOR RELIEF**

81. Plaintiff's "Prayer for Relief" section of the Complaint does not contain allegations of fact and therefore no responsive pleading is required. To the extent a response is deemed necessary, P&G and sanofi-aventis deny each and every allegation and assertion listed

under the "Prayer for Relief" section of Plaintiffs' Complaint and deny that Plaintiffs are entitled to any of the relief requested.

**AFFIRMATIVE DEFENSES**

82. Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable P&G and sanofi-aventis to determine all of their legal, contractual and equitable rights, P&G and sanofi-aventis hereby give notice that they intend to rely upon such other defenses as may become available or appear during discovery proceedings in this case and hereby reserve the right to amend and/or supplement this answer to assert any such defense at a future time and in conformity with the Federal Rules of Civil Procedure.

**FIRST AFFIRMATIVE DEFENSE**

83. The Complaint fails to state a claim upon which relief can be granted.

**SECOND AFFIRMATIVE DEFENSE**

84. Any product for which P&G and sanofi-aventis were responsible at the time of the occurrences or injuries alleged by Plaintiff was not defective and unreasonably dangerous in its design, manufacture, or marketing, and it was at all times reasonably safe and reasonably fit for its intended use. The warnings and instructions accompanying the product at issue in this case were legally adequate warnings and instructions.

**THIRD AFFIRMATIVE DEFENSE**

85. Plaintiff's claims are barred in whole or in part because P&G and sanofi-aventis provided adequate "direction or warnings" as to the use of any of its products within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**FOURTH AFFIRMATIVE DEFENSE**

86. P&G and sanofi-aventis assert the applicability of comment k of the Restatement (Second) of Torts § 402A, which bars Plaintiff's claims in this lawsuit.

**FIFTH AFFIRMATIVE DEFENSE**

87. P&G and sanofi-aventis deny that Plaintiff used any product manufactured or marketed by P&G and sanofi-aventis as alleged in Plaintiff's Complaint.

**SIXTH AFFIRMATIVE DEFENSE**

88. Any and all damages alleged by Plaintiff may have been caused by misuse of the product at issue, failure to use the product properly, and/or alteration or negligent use of the product.

**SEVENTH AFFIRMATIVE DEFENSE**

89. If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.

**EIGHTH AFFIRMATIVE DEFENSE**

90. The occurrences and injuries alleged by Plaintiff were caused or contributed to by the negligence, breaches of warranty, or defective products of third parties over whom P&G and sanofi-aventis had no control and for whom they are not responsible.

**NINTH AFFIRMATIVE DEFENSE**

91. Plaintiff's claims may be barred by negligence and/or the contributory negligence of others, and/or by the assumption of risks, if any, inherent in the alleged use of the product at issue by Plaintiff and/or the treating physicians and/or other health care providers.

**TENTH AFFIRMATIVE DEFENSE**

92. If Plaintiff sustained the injuries and damages alleged in the Complaint, such injuries resulted, in whole or in part, from the culpable conduct and negligence of Plaintiff and/or of third parties, not from any negligence or breach of duty by P&G and sanofi-aventis.

**ELEVENTH AFFIRMATIVE DEFENSE**

93. The occurrences and injuries alleged by Plaintiff resulted from an intervening cause or a new and independent cause which was the proximate and/or producing cause and/or the sole proximate and/or sole cause of the occurrences and injuries alleged by Plaintiff. Moreover, the occurrences and injuries were caused by separate and independent events or agencies not reasonably foreseeable. Such separate and independent events or agencies destroy the causal connection, if any, between any alleged breach of legal duty on the part of P&G and sanofi-aventis and the occurrences and injuries alleged by Plaintiff, and thereby become the immediate and/or sole cause and/or sole proximate cause of such occurrences and injuries, relieving P&G and sanofi-aventis of liability to Plaintiff or any other parties.

**TWELFTH AFFIRMATIVE DEFENSE**

94. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused, in whole or in part, by operation of nature or act of God.

**THIRTEENTH AFFIRMATIVE DEFENSE**

95. If Plaintiff sustained the injuries or incurred the expenses alleged, the same may have been caused by an idiosyncratic reaction, without any negligence, defect, or failure on the part of P&G and sanofi-aventis.

**FOURTEENTH AFFIRMATIVE DEFENSE**

96. If the Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and

environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses for which P&G and sanofi-aventis are not responsible.

**FIFTEENTH AFFIRMATIVE DEFENSE**

97. The Federal Food & Drug Administration (“FDA”) has implemented a comprehensive regulatory scheme governing the safety and efficacy of prescription drugs. The drug at issue in this case (the “product” or “product at issue”) was approved by the FDA pursuant to such applicable statutes and regulations and, pursuant to such, could only be used pursuant to the prescription of a licensed prescriber. The labeling for the product at issue was also approved by the FDA and the marketing was conducted in conformity with the FDA’s rules and regulations. To the extent Plaintiff asserts claims based on P&G and sanofi-aventis’ adherence to and compliance with applicable federal laws, regulations and rule, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTEENTH AFFIRMATIVE DEFENSE**

98. Plaintiff cannot recover because the product at issue was designed and/or made in accordance with the state of the art at the relevant time.

**SEVENTEENTH AFFIRMATIVE DEFENSE**

99. P&G and sanofi-aventis state that the benefits of the product at issue outweigh the risks, if any, which may be attendant to its use.

**EIGHTEENTH AFFIRMATIVE DEFENSE**

100. Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations.

**NINETEENTH AFFIRMATIVE DEFENSE**

101. Plaintiff's claims are barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**TWENTIETH AFFIRMATIVE DEFENSE**

102. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**TWENTY-FIRST AFFIRMATIVE DEFENSE**

103. To the extent that Plaintiff relies upon any theory of breach of warranty, Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**TWENTY-SECOND AFFIRMATIVE DEFENSE**

104. Actonel is a prescription pharmaceutical that was available only upon the prescription of a licensed physician, and persons other than P&G and sanofi-aventis, including Plaintiff's treating physicians and health care personnel and institutions, stood in the position of learned intermediaries between P&G and sanofi-aventis and Plaintiff. Any claims against P&G and sanofi-aventis accordingly are barred in whole or in part by the learned intermediary doctrine.

**TWENTY-THIRD AFFIRMATIVE DEFENSE**

105. Plaintiff's claims are barred as a matter of law pursuant to Restatement (Third) of Torts §§ 2,4, and 6.

**TWENTY-FOURTH AFFIRMATIVE DEFENSE**

106. Plaintiff's claims relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

**TWENTY-FIFTH AFFIRMATIVE DEFENSE**

107. This case is more appropriately brought in a different venue.

**TWENTY-SIXTH AFFIRMATIVE DEFENSE**

108. To the extent Plaintiff settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, P&G and sanofi-aventis' liability, if any, should be reduced accordingly.

**TWENTY-SEVENTH AFFIRMATIVE DEFENSE**

109. Plaintiff's claims are barred in whole or in part because Plaintiff has failed to mitigate the alleged damages.

**TWENTY-EIGHTH AFFIRMATIVE DEFENSE**

110. P&G and sanofi-aventis deny that they have been guilty of any conduct which warrants the issue of punitive damages being submitted to a jury.

**TWENTY-NINTH AFFIRMATIVE DEFENSE**

111. Any award of punitive damages to Plaintiff in this case would be in violation of the constitutional safeguards provided to Defendant under the Constitution of the United States of America.

**THIRTIETH AFFIRMATIVE DEFENSE**

112. With respect to Plaintiff's demand for punitive damages, P&G and sanofi-aventis specifically incorporate by reference any and all standards or limitations regarding the determination and/or enforceability of punitive damage awards which arose in the decisions of *BMW of North America v. Gore*, 116 U.S. 1589 (1996) (as extended by *Cooper Indus. v.*

*Leatherman Tool Group*, 532 U.S. 424 (2001)) and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003)).

**JURY DEMAND**

P&G and sanofi-aventis hereby demand a trial by jury on all of Plaintiff's claims.

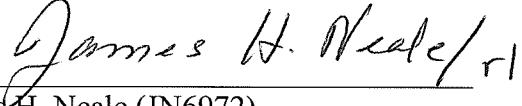
WHEREFORE, Defendants P&G and sanofi-aventis pray for judgment as follows:

1. That Plaintiffs take nothing by their Complaint;
2. For such other and further relief as the court may deem just and proper.

Dated: October 26, 2007

Respectfully submitted,

By:

  
James H. Neale (JN6972)

FULBRIGHT & JAWORSKI L.L.P.

666 Fifth Avenue

New York, NY 10103-3198

(212) 318-3000

*Attorney for Defendants Procter & Gamble  
Pharmaceuticals, Inc., and sanofi-aventis U.S.  
L.L.C.*

- AND -

Terry O. Tottenham

Lana K. Varney

FULBRIGHT & JAWORSKI L.L.P.

600 CONGRESS AVENUE, SUITE 2400

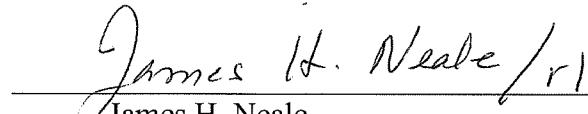
AUSTIN, TEXAS 78701

(512) 536-5201

*Of Counsel*

**CERTIFICATE OF SERVICE**

I certify that this document was served by U.S. Mail on October 26, 2007 on the following counsel:

  
\_\_\_\_\_  
James H. Neale

J. Paul Sizemore, Esq.  
Girardi / Keese  
1126 Wilshire Boulevard  
Los Angeles, CA 90017  
Tel. : (213) 977-0211  
Fax : (213) 481-1554

Catherine Heacox, Esq.  
The Lanier Law Firm, PLLC  
126 East 56th Street, 6th Floor  
New York, NY 10022  
Tel. : (212) 421-2800  
Fax : (212) 421-2878

Theodore VanHuysen Mayer, Esq.  
Hughes Hubbard & Reed LLP  
One Battery Park Plaza  
New York, NY 10004  
Tel. : (212) 837-6000  
Fax : (212) 422-4726